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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,962	11/29/2001	Robert Hanson	DOCUSY 3.0-007	4898
530 7590 08/09/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER COBANOGU, DILEK B	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 08/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/997,962

**Applicant(s)**

HANSON ET AL.

**Examiner**

Dilek B. Cobanoglu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/29/2001,6/4/2002,7/29/2002, 5/22/2007,6/29/2007.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment received on 05/10/2007.

Claims 17-18 have been canceled. Claims 1, 8, 16, 27 and 31 have been amended.

Claims 1-16, 19-36 remain pending in the application.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-16, 19-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775) in view of Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,857,716).

A. Claim 16 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

- i. providing a source of a drug to be administered to a patient  
(Walker; abstract, col. 2, lines 7-19),
- ii. associating a unique tracking code with said source, providing data associated with said drug to be administered (Walker; abstract, col. 2, lines 7-19),

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- iii. storing said data in association with said tracking code on a storage device, whereby said data may be altered while still being associated with the same unique tracking code, and
- iv. retrieving said data from said storage device using said tracking code.

- Walker fails to expressly teach storing said data in association with said tracking code on a storage device, whereby said data may be altered while still being associated with the same unique tracking code, and retrieving said data from said storage device using said tracking code. However, this feature is well known in the art, as evidenced by Gombrich.

In particular, Gombrich discloses storing said data in association with said tracking code on a storage device, whereby said data may be altered while still being associated with the same unique tracking code, and retrieving said data from said storage device using said tracking code. (Gombrich; abstract, col. 8, lines 4-30, col. 8, line 66 to col. 9, line 7, col. 12, lines 48-51, col. 13, line 57 to col. 14, line 21, col. 16, lines 21-27).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned

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limitation as disclosed by Gombrich with the motivation of to provide more reliable and safe treatment of patients.

B. Claims 17-18 have been canceled.

C. Claims 19-26 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 19-26 are rejected for the same reasons given in the previous Office Action (page numbers 3-4), and incorporated herein.

D. Claim 27 has been amended to recite "retrieving said data from said storage device using said tracking code"

- The obviousness of modifying the teaching of Walker to include retrieving said data from said storage device using said tracking code (as taught by Gombrich) is as addressed above in the rejection of claim 16 and incorporated herein.

E. Claims 28-30 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 28-30 are rejected for the same reasons given in the previous Office Action (page numbers 4-5), and incorporated herein.

F. Claim 31 has been amended now to recite "a storage and retrieval device for storing and retrieving data related to said drug in association with said tracking code, said tracking code adapted to retrieve said data from said storage and retrieval device".

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- The obviousness of modifying the teaching of Walker to include retrieving said data from said storage and retrieval device" (as taught by Gombrich) is as addressed above in the rejection of claim 16 and incorporated herein.

G. Claim 1 has been amended now to recite a medical device for the administration of a drug, said device comprising:

- i. a source of a drug to be administered to a patient,
- ii. a holder for said source, and
- iii. a tracking code located on at least one of said source and said holder (Walker; col. 2, lines 29-35), said tracking code being a unique identifier associated with the identification of said drug to be administered from said source (Walker, abstract, col. 2, lines 7-19), wherein said tracking code enables the tracking of all data to be stored on a remote storage device relating to said drug being administered without alteration of said tracking code, said tracking code adapted to retrieve said data stored on said storage device.

- The obviousness of modifying the teaching of Walker to include tracking code enables the tracking of all data to be stored on a remote storage device relating to said drug being administered without alteration of said tracking code, said tracking code adapted to retrieve said data stored on said

storage device (as taught by Gombrich) is as addressed  
above in the rejection of claim 16 and incorporated herein.

H. Claims 2-7 and 9-15 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 2-7 and 9-15 are rejected for the same reasons given in the previous Office Action (page numbers 4-5), and incorporated herein.

I. Claim 8 has been amended now to recite a syringe label cradle unit comprising:

- i. a syringe label cradle,
- ii. a syringe attached to said cradle, the syringe adapted to hold a drug to be administered to a patient, and
- iii. a tracking code affixed to at least one of said cradle and said syringe, said tracking code being a unique identifier associated with the identification of said drug to be administered from said source (Walker; abstract, col. 2, lines 7-19, lines 29-35), wherein said tracking code enables the tracking of all data to be stored on a remote storage device relating to said drug being administered without alteration of said tracking code, said tracking code adapted to retrieve said data stored on said storage device.

- Walker fails to expressly teach tracking code enables the tracking of all data to be stored on a remote storage device relating to said drug being administered without alteration of



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said tracking code, said tracking code adapted to retrieve said data stored on said storage device. However, this feature is well known in the art, as evidenced by Gombrich. In particular, Gombrich discloses tracking code enables the tracking of all data to be stored on a remote storage device relating to said drug being administered without alteration of said tracking code, said tracking code adapted to retrieve said data stored on said storage device. (Gombrich; abstract, col. 8, lines 4-30, col. 8, line 66 to col. 9, line 7, col. 12, lines 48-51, col. 13, line 57 to col. 14, line 21, col. 16, lines 21-27).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Gombrich with the motivation of to provide more reliable and safe treatment of patients.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
5. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC  
Art Unit 3626  
08/01/2007

  
C. LUKE GILLIGAN  
PRIMARY EXAMINER  
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